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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,859	05/11/2001	Charles Jack Fisher	X-12451	7153

25885 7590 09/26/2002

ELI LILLY AND COMPANY  
PATENT DIVISION  
P.O. BOX 6288  
INDIANAPOLIS, IN 46206-6288

EXAMINER
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WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/26/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/853,859

Applicant(s)

FISHER ET AL.

Examin r

Jon P. Weber, Ph.D.

Art Unit

1651

-- The MAILING DATE f this communicati n appears on the cover sheet with the correspondence address --

## Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 11-17 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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*Status of the Claims*

Claims 11-17 have been presented for examination.

*Specification*

The disclosure is objected to because of the following informalities: At page 15, the example is labeled "1" which has already been used. It is believed that this should be example "4".

Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method for treating heparin-induced thrombocytopenia (HIT) by administration of activated protein C (APC). However, despite the suggested amounts of APC to be used in such therapy there are no working examples demonstrating that this therapy actually works as claimed. Example 4 is a proposed clinical trial. No results are presented. The very language, "This trial aims to show ..." attests to the prophetic nature of this example.

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The lack of a working example must be considered in view of the showing in Gardyn et al. (1995) that a patient with resistance to APC died of HIT. Given that the patient is resistant to APC, there a person of ordinary skill in the art would not administer APC to such a patient effected by HIT. This "abnormal response to APC" is said to occur in 20-30% of patients with unexplained thrombosis. Gardyn et al. say that there is no clear association between thrombosis and HIT known in the art. However, their data is said to suggest that there might be a correlation between HIT and thrombosis in APC resistant patients.

Absent some teaching in the disclosure of when it is safe to administer APC to a patient affected by HIT, a person of ordinary skill in the art would not be reasonably apprised of when and how to administer APC to treat HIT. Accordingly, the claims are not deemed to be enabled by the specification disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 depends from canceled claim 1. It is believed that it was intended to depend from claim 11 and was examined as such.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drohan et al. (US 5,589,604) or Lubon et al. (US 5,831,141).

Drohan et al. (US 5,589,604) at column 1, lines 41-46 and Lubon et al. (US 5,831,141) at column 1, lines 53-67, disclose that heparin-induced thrombocytopenia is one of several clinical situations which may benefit from administration of protein C. Drohan et al. (US 5,589,604) or Lubon et al. (US 5,831,141) lack specifying the effective amounts or administration means.

A person of ordinary skill in the art at the time the invention was made would have been motivated to administer APC to treat HIT as taught by Drohan et al. (US 5,589,604) or Lubon et al. (US 5,831,141) at effective dosages and regimens because, as admitted at page 8 of the disclosure, persons "skilled in the art can readily optimize pharmaceutically effective dosages and administrative regimens for therapeutic compositions comprising protein C."

Hence, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to optimize the effective dosages and administration regimens for administering APC to treat HIT as suggested by Drohan et al. (US 5,589,604) or Lubon et al. (US 5,831,141).

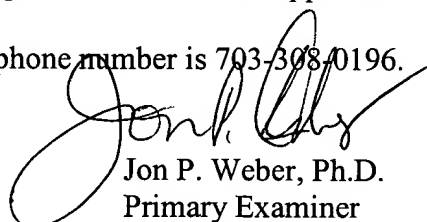
No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
September 25, 2002